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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/443,070	11/18/1999	TERRY L. GILTON	3530.2US	6721

7590 05/16/2002

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EXAMINER

GABEL, GAIENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 05/16/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/443,070	GILTON, TERRY L.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,8 and 12-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,8 and 12-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's Response

1. Applicant's response filed 3/5/02 in Paper No. 18 is acknowledged. Currently, claims 1-2, 8, and 12-31 are pending and under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 102

2. In light of Applicant's argument, the rejection of claims 18, 21, and 26-29 under 35 U.S.C. 102(e) as being anticipated by Northrup et al. (US 5,882,496) is, hereby, withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2, 8, and 12-31 stand rejected under 35 U.S.C. 102(b) as being anticipated by Swedberg et al. (US 5,571,410) for reason of record.

To reiterate, Swedberg et al. disclose a miniaturized planar column device for use in chromatographically or electrophoretically separating and analysing analytes in a

Art Unit: 1641

mobile phase (see Abstract and columns 12-14). The miniaturized columns are formed (laser ablated) into a substantially planar nonporous substrate (see column 11, lines 4-62 and column 15, lines 43-55). The substrate comprises polyamides such as nylons, polyimides, polyolefin compounds, and polymethylmethacrylate (see column 21, line 49 to column 22, line 4). Swedberg et al. specifically disclose that the miniaturized columns may have porosity formed thereto (sample treatment component) by incorporating a porous medium comprising particles or membranes made from polyamides such as nylon, or polymethylmethacrylate; thus, forming a biocompatible porous matrix having the same material as the nonporous substrate (see column 27, lines 33-43). The matrix performs both a filtration function and a capture function. The capture substrate formed includes antigens (biological affiant), antibody, lectin, enzyme substrate, capture oligonucleotide, etc. (see column 27, lines 44-61). Swedberg et al. also disclose that each miniaturized column has a detector disposed proximate a detection region (see column 4, lines 52-67, columns 8-9, and column 17, lines 31-45). The device allows a variety of drawing (injection or motive force) methods including application of differential pressure (pressure injection), capillary action (hydrodynamic injection), and electrical current (electrokinetic injection or electroosmotic flow) (see column 5, lines 4-13, column 11, lines 58-63, and column 17, lines 47-64). Swedberg et al. also disclose a "LIGA" process wherein microstructures having high aspect ratios and increased structural precision and uniformity in channels ports, apertures, and microalignment means are fabricated into the device (see column especially column 13, lines 9-33). In Example I, Swedberg et al. exemplify separation and determination of

Art Unit: 1641

immunoglobulins wherein assay and detection reagents are incorporated into the device during analysis.

Response to Arguments

4. Applicant's arguments filed 3/05/02 with regards to the rejection of the claims as being anticipated by Swedberg, have been fully considered but they are not persuasive.

A) Applicant argues that Swedberg does not anticipate the claimed invention because Swedberg discloses a miniaturized column device that is formed by laser ablating a substrate that is "any material which is UV-adsorbing, and which is not silicon or silicon dioxide such as polymers, ceramics, and laminates". According to Applicant, these materials are used to avoid the problems encountered in silicon and silicon dioxide-based materials.

In response, claims 1 and 18, and all claims dependent therefrom, recite that the capillary column is "formed in a nonporous substrate" which does not exclude "laser ablating a substrate comprising polymers, ceramics, and laminates". Claims 1 and 18 further does not exclude that the nonporous substrate is not silicon or silicon dioxide material.

B) Applicant argues that Swedberg lacks any express or inherent description of applying a sample to and drawing the sample across a flow front through a matrix of a porous capillary column that is formed in and from the same material as the nonporous substrate.

Art Unit: 1641

In response to Applicant's argument that the porous matrix of the capillary column is **formed in or from the same material as** the nonporous substrate, it is noted that independent claims 1 and 18, and all claims dependent therefrom, recite that the "porous capillary column comprises a matrix including the same material as the nonporous substrate". Swedberg, indeed, discloses that the porous matrix is formed in and from the same material as the nonporous substrate. Specifically, Swedberg discloses in column 21, line 49 to column 22, line 4, that the nonporous substrate comprises polyamides such as nylons, polyimides, polyolefin compounds, and polymethylmethacrylate. Further in column 7, lines 33-43, Swedberg discloses that the miniaturized columns may have porosity formed thereto by incorporating a porous material comprising particles or membranes made from polyamides such as nylon, or polymethylmethacrylate; thus, forming a biocompatible porous matrix having the same material as the nonporous substrate.

Alternatively, if Applicant intends that the porous matrix is formed from the same material comprising or consisting of the nonporous substrate, i.e. by porifying the nonporous substrate, it is noted that such a recitation is not reflected in the rejected claims.

C) Applicant's arguments filed 3/05/02 with regards to the rejection of claims 18, 21, and 26-29 as being anticipated by Northrup, have been fully considered and are deemed persuasive. Accordingly, the rejection has been withdrawn.

Art Unit: 1641

5. For reasons aforementioned, no claims are allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

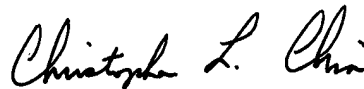
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Art Unit: 1641

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gailene R. Gabel
May 14, 2002



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1808~~/641